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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,921	06/28/2001	Udit Batra	20243CA	1812

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/894,921	BATRA ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 48-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 48-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 7, 2004 has been entered.

Claims 1, 48-64 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1,48-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makooi-Morehead US Patent 6,238,695 in view Remington: the Science and Practice of

Pharmacy 19th edition (pages 1616-1620) (IDS, filed June 28, 2001 or Phipps US Patent 5,260,073.

Makooi discloses compressed effavirenz tablets comprising 300mg of efavirenz (50% by wt), sodium lauryl sulfate which is a surfactant, microcrystalline cellulose which is a filler/disintegrant, sodium starch glycolate or croscarmelose sodium which is a superdisintegrant, lactose which is a filler/compression aid and magnesium stearate which is a lubricant (see abstract; col 5, lines 16; col 7, lines 15-67; claims 12-15). Makooi teaches concentrations of efavirenz of 300 to 800 mg per tablet (see col 5, lines 36-39; claim 14). Makooi teaches the use of superdisintegrants in the art in amounts ranging between 1-10%. (see col 3, lines 35-40).

Makooi employs a wet granulation process to prepare his formulations (see col 5, lines 59-col 6, line9; example 3). Thus, Makiooi's formulation would also contain a solvent such as water or ethanol to form an aqueous solution. (see col 5, lines 60-67; col 7, lines 19-20). Makooi's methods employs the same steps as the instantly taught, therefore, the final product of Makooi inherently contains and meets all limitations of the instant tablets.

Further, with respect to claims 57-64 Examiner states that the instant claims appear to be drafted as "product by process" claims. Accordingly, products by process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (see MPEP 2113). "Even though product - by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of

production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). Absent a clear structural or compositional difference, the products are viewed to be an obvious modification of the prior art.

Makooi fails to specifically employ 1-5 percent superdisintegrant or employ hydroxypropylcellulose as a binder.

Remington provides teachings for various types of pharmaceutically acceptable excipient that may be used to formulate compressed tablets (pages 1616-1620). For example, Remington on page 1618 sets forth binders such as various types of cellulose derivatives including hydroxypropylcellulose, or other types of binders such as starch or PVP are recognized in the art as art equivalent.

Phipps is also used to show that in formulating compressed tablets binders include polymeric binders such as hydroxypropylcellulsoe and disintegrants include croscarmellose, microcrystalline cellulose or crospovidone (see col 54-67).

Although Makooi's teachings does not specifically teach the instant concentrations of superdisintegrants or the use of hydroxypropylcellulose as the binder of choice, it would have been obvious to one of ordinary skilled in the art of dosage formulation to optimize the individual ingredients of Makooi's dosage forms by routine experimentation and further substitute any suitable art equivalent moiety known in the art such as hydroxypropylcellulose, as taught in Remington or Phipps, for the binder of Makooi to improve the pharmacokinetic characteristics of Makooi's dosage formulation.

Response to Arguments

Applicant's arguments filed on September 7, 2004 have been fully considered but they are not persuasive. As has previously discussed on the record, Applicant argues that Makooi does not teach the instant amount of superdisintegrant. (Arguments at pages 5-6).

In response, Examiner states that the issue disputed here is not whether Makooi uses superdisintegrants in amounts of 1-5 wt%, rather, whether the scope of the instant claims are limited to such range. Examiner has previously reasoned tha applicant's position is based on an illusory distinction between the scope of the instant disintegrants and superdisintegrants, because neither the specification nor the art draws a distinction between the scope of the instant disintegrant and superdisintegrants. (see Final Rejection filed on June 7, 2004).

Attention is drawn to the scope of the instant claim 1. The instant tablet must contain both filler/disintegrant and superdisintegrant. The Specification at gage 3 defines the scope of disintegrants and superdisintegrants. Accordingly, superdisintegrants encompass all disintegrants listed in the instant specification (see page 3, lines 8-13, and lines 23-26). Further, the specification fails to close the definition of superdiintergrants to any particular subgenus of disintegrants. Rather it clearly states that "Examples of superdisintegrants include the disintegrants listed above, carboxymethylcellulose sodium, croscarmellose sodium, povidone, guar gum etc..." (see Specificaiton at page 3, lines 24-27). Since microcrystalline cellulose falls within

the scope of the superdisintegrants as defined in the specification, the instantly claimed tablets can contain a total amount of about 25% superdisintegrants/disintegrant.

Applicant also attempts to narrow the scope of the term superdisintegrants from what has originally been recited in the specification at page 3, lines 21-27. (see Arguments at page 6, 2nd para.). Applicant then argues that "lines 21-27 of page 3 states that certain of the disintegrants listed above at lines 8-13 are superdisintegrants,.." (see Arguments at page 6, lines 6-10).

Such attempts to narrow the scope of the term "superdisintegrant" appear to constructively amount to a new matter, which was not originally envisioned in the specification. The statement referred to in the specification is an inclusive description of superdisintegrants, not an exclusive description. Therefore, for the reasons set forth above, the differences between the term disintegrants and superdisintegrants is still viewed to be illusory, because same disintegrants falling within the definition of superdisintegrants can be added to the instant tablets to yield a higher percentage of the superdisintegrant.

Furthermore, the art appears to characterize superdisintegrants and disintegrants as art recognized functional equivalents. See for example Phipps at col 8, lines 59-64 or Remington at page 1619. Accordingly, croscarmellose is expected to provide similar function as alginic acid or microcrystalline cellulose. Thus, even the state of art appears to view the difference between the superdisintegrants and disintegrants illusory. Applicant has not provided any evidence to show otherwise.

Finally, Applicant argues that even though Makooi teaches the use of superdisintegrants in amounts of 1-10wt% in the art, such teachings is not an embodiement of the invention being claimed by Makooi (see Arguments at page 7, 3rd para.). In response, Examiner that Makooi's teachings are not a direct teaching away from the instant claims. Thus, Applicant's conclusion is not correct.

Here, Applicant appears to misinterpret what it means to "teach away" from a patented invention. Generally, "disclosed examples and preferred embodiments do not constitute a teaching which is away from a broader disclosure or nonpreferred embodiments." *In re Susi*, 169 USPQ 423 (CCPA 1971). "In general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the results sought by the applicant." *In re Gurley,* 31 USPQ2d 1130, 1131-2 (Fed. Cir. 1994).

Here, the mere fact that Makooi teaches an alternative means of improving drug delivery, as described by higher concentrations of superdisintegrants in his composition, does not preclude optimization of the amounts of superdisintegrant. Further there is no direct statement that low levels of superdisintegrants would not be suitable with efavirnez. Thus, applicant's arguments are not persuasive.

Declaration Under 37 CFR 1.132

The Declaration under 37 CFR 1.132 filed on October 2003 is sufficient to overcome the rejection of claim 56 based upon the results, because of the reasons set forth in the Office Action mailed on June 7, 2004. However, the declaration is not commensurate with the scope of all other pending claims.

Claim Objection

Claim 56 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, because the scope of such .

Allowable Subject Matter

Claim 56 is free of art in view of the unexpected results presented in the declaration under 37 CFR 1.132 filed on Oct 06, 2003.

Claim 56 would be allowable if rewritten or amended to overcome the objection, set forth in this Office action.

Recommendations

Throughout the prosecution Applicant appears to argue that no embodiment of the instantly claimed compositions can contain the same moiety as a disintegrant and superdisintegrant or no embodiment of the instantly claimed composition can contain a disintegrant which would also fall within the scope of the instant superdisintegrants. Based on such assumption, Examiner recommends that the generic claims 1 and 57 be limited to the specific disintegrants and superdisintegrants to the extent that they clearly exclude each other.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER